REMARKS

Based on the Advisory Action dated November 28, 2005, claims 1-27 of the subject application stand rejected solely under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,358,729 to Ohkuma et al. ("Ohkuma") in view of U.S. Patent 2,287,599 to Bulfer et al. ("Bulfer"). Applicant has amended claims 1, 23, 24, and 27, and canceled claims 2 and 23 herein. Claims 5, 8, 11, and 17 were previously canceled. Accordingly, claims 1, 3, 4, 6, 7, 9 10, 12-16, 18-24, 26 and 27 are pending in the application.

Applicant submits that the present amendment obviates the obviousness rejection for the reasons set forth hereafter. Support for the amendments to claims 1, 24, and 27 may be found in the second sentence of paragraph [0030] and in various places in the application including the originally filed claims 4 and 5. The amendment to claim 23 corrects defects in the claim language but does not change the subject matter of the claim.

In response to the Advisory Action, Applicant filed a Notice of Appeal and Pre-Appeal Brief Review Request on December 13, 2005 under the program announced in the *Official Gazette* of July 12, 2005. The Review Panel issued its finding that the application remains under appeal on January 27, 2006, thereby setting the deadline for filing an Appeal Brief to February 27, 2006.

In a discussion with Mr. Anton Fetting of the United States Patent & Trademark Office ("USPTO"), who is listed in the USPTO OG Notice of 12 July 2005 as the USPTO contact person regarding the Pre-Appeal Brief Review Program, Mr. Fetting indicated that an RCE under 37 C.F.R. 1.114 may be filed during the time limit for filing the Appeal Brief after receipt of the Decision of the Review Panel. Thus, pursuant to

Applicant's conversation with Mr. Fetting and MPEP 706.07(h)(X), Applicant's filing of a this RCE under 37 C.F.R. 1.114 is proper and shall be treated as a withdrawal of the appeal by the applicant.

As an initial matter, Applicant's representatives acknowledge the decision of the Pre-Appeal Panel mailed January 17, 2006, wherein the Panel declined to pass the then pending claims on to allowance but acknowledged they were in condition for appeal. Although Applicant disagrees with the rejections set forth by the Examiner for the prior claims for the reasons of record, the claims have been amended as set forth herein to pursue particular embodiments of the invention. Applicant expressly reserves, however, the right to pursue the original claims in a continuation application at a later date.

Prior to discussing the claims and grounds of rejection in details, Applicant wishes to briefly summarize the objectives, problems solved and advantages provided by Applicant's invention in view of the cited art.

Applicant's Invention

The objective of Applicant's invention is to prepare commercially desirable, indigestible dextrins for use as a food additive by acid hydrolysis of starch using economical and efficient techniques. To be commercially desirable as a food additive, the indigestible dextrin itself (not a subsequently combined product) should lack coloration, i.e., have certain minimum "whiteness" level. It has been commercially recognized that the whiteness should be between 50 and 100 and more preferably between 60-100 when measured using the Kett Co. apparatus mentioned in the specification at paragraph 0040 and in the cited art by Ohkuma at column 23, line 21.

To be economical and efficient, the process should yield a product with as much indigestible dextrin as is possible from the starting starch material, use as little energy as possible, and avoid subsequent processing steps, such as decolorization steps to make the product commercially desirable.

Unfortunately, the forgoing objectives are in tension with one another. To make a product with indigestible dextrin in high yield, higher temperatures should be used for the acid hydrolysis. This is expressly recognized by Ohkuma at column 15, lines 18-20 based on the data in Table 4. Whiteness, on the other hand, is inversely related to processing temperature (the higher the temperature the less whiteness that is obtained). This inverse relationship between temperature and whiteness is expressly recognized by Ohkuma at column 23, lines 38-39 based on the data in table 13. Thus, higher temperatures lead to better yield but at the cost of higher energy cost and inferior whiteness quality, while lower temperatures lead to better whiteness and lower energy costs, but produce lower yield of the indigestible dextrin.

Applicant was the first to recognize and reduce to practice, a practice that balances the need between production efficiency and whiteness based on a nexus between temperature and whiteness that is a function of pH. More specifically, Applicant has surprisingly discovered that there is an optimum pH to be selected between 1-4, and more preferably between 2 and 3, based on different temperatures that may be selected between 140°C and 180°C that will allow one to obtain an optimum yield of dextrin of a preferred whiteness level of between 60 and 100. (*See* for example, paragraphs [0038]-[0040] of the specification). Importantly, in preferred

embodiments, the pH is obtained using hydrochloric acid as stated in paragraph [0030] of the specification.

Turning now to the exemplified results in Figure 1 of the application, the data shows that the optimum pH for obtaining a dextrin with a whiteness level of 65 differs for temperatures between 140°C and 170°C, that the optimum pH tends to be lower when the temperature is higher, and that in each case the optimum pH falls within a narrow range of between 2 and 3, and most narrowly between about 2.2 and about 2.7. Note that although the highest yield of dextrin obtained by Applicant (at 170° C) is only about 62.5% in comparison to the 90.1% obtained by Ohkuma at that temperature disclosed in Table 4 of Ohkuma, one benefit of Applicant's invention is that the dextrin obtained by Applicant's method has the commercially desirable property of high whiteness – a value greater than 60 - which is not obtained by Ohkuma using any temperature within the range recited by Applicant. To illustrate, turning to Table 13 of Ohkuma, it is disclosed that at 170°C the whiteness obtained according to that reference was only 21.3. At the highest end of Applicant's recited range (i.e., 180°C) the whiteness obtained by Ohkuma is worse at 20.5. Even at the lower end of Applicant's range (i.e., 140°C) the highest whiteness disclosed by Ohkuma is only 50.5.

Thus, Applicant's invention has met a long felt commercial need to optimize dextrin production by balancing the need for high yield against the opposing need to obtain a product of commercially acceptable whiteness level. Indeed, presently the commercial processes utilized by the assignee of the present application are based on Applicant's invention and produces a dextrin having a whiteness of about 70 using a pH of about 2.4 and a temperature of about 160 degrees. Ohkuma, which is the closest

prior art, fails to accomplish high whiteness in the temperature ranges recited by Applicant. This commercial success of Applicant's invention in comparison to the closest prior art is evidence of "commercial success, long felt but unresolved needs, failure of others, etc." that as have long since been established by the U.S. Supreme Court as objective indicia of non-obviousness (*Graham v. John Deere Co.,* 383 U..S.1 at 17 (1966)).

This long felt need is not met by the teaching of Ohkuma or Bulfer, alone or in combination, nor is there any suggestion in either reference that pH is in any way a critical parameter to manipulate to achieve a desired whiteness level of an indigestible dextrin food additive, especially where selecting the pH that is optimal for dextrin production differs for different temperatures.

Ohkuma

To illustrate the deficiency in Ohkuma, that reference merely recognizes that whiteness is a desired property, or more specifically, that colored substances are not desired for food quality dextrins. However the reference teaches nothing at all about relationship of pH to whiteness. As discussed in Applicant's previous Responses, the <u>only</u> places in the entire reference that discuss colored substances or effects on whiteness are in the following places:

At column 6, lines 62-66 Ohkuma teaches:

> Higher reaction temperatures result in increases in the content of indigestible component, but very high temperatures are not desirable since the product contains an increased amount of colored substance when the temperature exceeds about 170° C. Stated specifically, the reaction temperature is 120° to 200° C., preferably 130° to 180°C., more preferably 140° to 180°C.

At column 23, beginning at line 38 Ohkuma teaches:

> The whiteness decreased generally in inverse proportion to the heating temperature or heating time. However, the whiteness of comparative example 1 is such lower that of the products of present invention. This reveals that the conventional products were not practically useful.

At column 29, line 4 Ohkuma teaches that:

> As the heating temperature rises, the product contains a larger amount of colored substance, resulting in the whiteness level lowering to about 20% which is considered to be the lower limit for use of the product as a food material. Thus, the heating temperature is limited for the use of the product.

At column 29, beginning at line 62 Ohkuma teaches:

> The product as heat-treated by the extruder contains hydrochloric acid and therefore needs to be neutralized and thereafter refined, for example, by decoloration with activated carbon, filtration and desalting with ion exchange resin when to be used for purposes other than feeds. However, if the material starch is heated in the extruder at high temperatures over 180° C., an increased amount of colored substance will result to impair the quality of the product in spite of neutralization and purification. The product is accordingly undesirable for use in foods.

At column 34, beginning at line 26 Ohkuma teaches:

> *The resulting product was decolorized with active carbon*, filtered, desalted with a mixed bed of ion exchange resin, decolored with active carbon again and filtered.

Taken together for what Ohkuma teaches <u>in entirety</u>, these sections at most teach that high temperatures (above 170° C) are to be avoided to limit the amount of colored substances and that a decolorization step is nevertheless needed to remove undesired colored products. In contrast, the avoidance of a decolorization step is precisely one of the principle commercial advantages of Applicant's invention which recognizes the critical effect of pH on whiteness. There is absolutely no teaching anywhere in Ohkuma related to an effect of pH on whiteness or color.

As set forth in Applicant's previous responses, in this regard the Examiner's prior citation of Figures 2 and 3 of Ohkuma is completely inapposite to any teaching on use

of pH to avoid color or increase whiteness *during* the *production of dextrin.* These Figures are discussed in the single context taught at column 35, beginning at line 60 where Ohkuma teaches:

> To 10% aqueous solution of indigestible dextrin was added 1% (based on solids) on glycine, and the mixture was heated at 100° C. for 150 minutes and checked for changes in the degree of coloration. The results achieved at pH of 4.5 and pH of 6.5 are shown in FIGS. 2 and 3, respectively. The same symbols as in FIG. 1 were used in these drawings.
>
> The indigestible dextrin is not greatly different in the increase of coloration degree from glucose or maltose. This indicates that the indigestible dextrin is usable generally in the same manner as these materials.

As emphasized by the underlined text, this section expressly refers to testing the affects of heating an already produced dextrin in the presence of an amino acid to see how much color the resulting product would have in comparison to heating the amino acid in the presence glucose or maltose. This is to determine the Ohkuma dextrin's usefulness in food products containing amino acids in comparison to glucose or maltose. The section plainly has nothing to do with the effect of pH on the production of the dextrin itself. It is improper hindsight the examiner to read more into this section than what the ordinarily skilled person recognizes as plainly taught or suggested therein to support a rejection based on obviousness.

Not only does Ohkuma altogether fail to teach any relationship of pH to whiteness in dextrin production, there is no example or process taught anywhere in Ohkuma that would lead one of skill in the art to acidify the starch with hydrochloric acid to obtain a pH of 1-4 in combination with using a temperature of 140-180 degrees to produce the dextrin. While Ohkuma teaches reaction temperatures in Applicant's recited range, it altogether fails to teach Applicant's recited pH range and whiteness

levels. In each example or discussion of acidifying the starch taught by Ohkuma, the starch is treated with 1% hydrochloric acid in an amount of 17.5 liters with 240 kg of starch, or in the amount of 22.5 liters with 300 kg starch, where in each case the slurry is brought to a moisture content of about 8%. It is elementary to calculate that the pH of the 1% hydrochloric acid is 0.54. Because starch is a neutral substance and an 8% moisture content is too low to dissolve the starch into solution, and because pH is a concentration measurement wholly dependent on solution volume, the pH of the starch slurries taught by Ohkuma will never be greater than about 0.54. Indeed, because the slurry is dried to a moisture content of 8%, the only effect that could possibly result is to further concentrate the solution component, which would further lower the pH.

This difference in pH explains why Ohkuma fails to achieve a whiteness level of 60-100 at any temperature between 140° and 180°C. For example, Table 13 of Ohkuma (column 23) shows that at temperatures within applicant's range, the whiteness level decreases from a maximum of 50.5 to a minimum of 20.5 as temperature is increased. Inspection of Figure 1 of Applicant 's specification shows that the pH range for optimal production with a whiteness of 65 falls within a very narrow range and that production levels fall quickly on either side of the optimal range. The ordinarily skilled person would recognize that the likely cause for the large difference in whiteness achieved by Ohkuma in comparison to Applicant's invention at the same temperature ranges must be due, at least in part, to the difference in pH.

Bulfer

Turning now to Bulfer, as discussed in the record before, that reference also fails to teach or suggest anything about a relationship of pH on whiteness of a dextrin. The

Bulfer reference merely provides the general teaching that a white dextrin can be produced with several superior properties for use as an adhesive paste by hydrolyzing the starch with a mixture of chlorine gas and monochloro acetic acid *instead of conventional use of other hydrolytic agents including, expressly, hydrochloric acid.* (See, column 1 paragraph 4). Bulfer nowhere teaches that pH affects whiteness, but merely that the whiteness of the film formed by using the paste is one of several general properties that may be improved by using chlorine gas and monochloro acetic acid instead of hydrochloric acid and other conventional hydrolyzing agents.

Bulfer teaches using monchloro acetic acid to acidify the starch to a pH of about 2.7 in a first step and using chlorine in a second step, which brings the mixture to a pH of about 2.5 that further includes heating to a temperature to a maximum high of 149° C. However, Applicants submit there is absolutely nothing that suggests that pH has an affect on the whiteness of the product, but rather, Bulfer teaches that using the mixture of chlorine and monochloroacetic acid produces all the beneficial effects.

Even assuming arguendo that one of skill in the art would think that use of dextrin as an adhesive according to Bulfer is related to use of dextrin as a food additive and would therefore use the technique of Bulfer to acidify starch using monochloro acetic acid and chlorine to affect the whiteness, Bulfer specifically and expressly teaches away from using hydrochloric acid. The teaching away begins in the aforementioned fourth paragraph of column 1, lines 19-28, where Bulfer states:

> The ordinary converting agents used for the production of dextrine from starch are hydrochloric acid, nitric acid, acetic acid, chlorine gas and caustic soda.
>
> The present invention is based upon the discovery that the dextrinization process may be shortened and/or dextrinization affected at a lower

> temperature <u>if in place of any of these agents, one uses a mixture of monochlor acetic acid and chlorine gas</u>. (emphasis added)

Bulfer further goes on at length to discuss the superiority of the product produced by the technique using chlorine gas and monchloro acetic acid especially against the use of conventional agents like hydrochloric acid, even going as far as providing a theory as to why the former combination is superior at the first paragraph on page 2, lines 1-14, where Bulfer teaches:

> The reason why a mixture of monchlor acetic acid and chlorine <u>acts more efficiently than hydrochloric acid or</u> than the other common dextrinization agents has not been fully demonstrated. The theory is that the chlorine gas reacts with the monchlo acetic acid *to form higher chlor actic acids such as dichlor or trichlor acetic acid and that these higher chlorinated acetic acids bring about the conversion at the lower temperatures and the production of dextrins having the above mentioned superior properties.* (emphasis added)

The underlined text emphasizes the teaching away from hydrochloric acid, while the italicized text emphasizes the theory of operation, i.e., formation of higher chloroacetic acids – which clearly cannot occur if one uses hydrochloric acid.

Accordingly, Bulfer's specific and express emphasis of the superiority of using monchloro acetic acid instead of hydrochloric acid is a direct teaching away from using hydrochloric acid. Thus, even assuming arguendo that the skilled person would be motivated by the teaching of Bulfer in combination with Ohkuma to hydrolyze starch at a pH of 2.5-2.7 and temperature of up to 149°C as taught by Bulfer to obtain an indigestible dextrin for food as taught by Ohkuma, that same skilled person is specifically taught by Bulfer to <u>not use hydrochloric acid, but to use chlorine and monochlor acetic acid instead</u>. The teaching away in the reference cannot be more clear and direct.

The Claims

Turning now to the claims, each of independent claims 1, 24 and 27 recite in pertinent part and form:

> ....*selecting a reaction temperature* of about 140°C to about 180°C;
>
> .....acidifying unmodified starch to a selected pH of about 1 to about 4 with hydrochloric acid, *wherein said selected pH is optimum to convert said unmodified starch to resistant starch when at said reaction temperature*; ...
>
> [and]
>
> .....maintaining said acidified unmodified starch close to said reaction temperature until a maximum yield of resistant starch has been obtained *while maintaining a whiteness level between about 60 and about 100.*

The italicized text emphasizes the combination of elements not taught or suggested by Ohukuma or Bulfer, alone or in combination. More specifically, neither reference teaches any impact of pH on whiteness, nor any nexus between pH and *selected temperature* that would allow one to se*lect a pH to optimally convert the starch to resistant starch* while about 60 and 100. In addition, Bulfer specifically and expressly teaches away from using *hydrochloric acid* to form a dextrin. Ohkuma teaches that higher temperatures give products having reduced whiteness and discloses that dextrin made at temperatures above 140°C have whiteness levels of less than 50.5%. Moreover, evidence of non-obviousness is supported by the objective indicia of commercial success of Applicant's invention and failure of others, – Ohkuma in particular – to obtain resistant starch at the recited whiteness levels using the temperature levels recited by Applicant.

Moreover, the dependent claims further recite process parameters not taught by either reference. By way of example and not limitation, claim 7 recites in pertinent part: "... wherein said optimal pH of acidified unmodified starch of step (b) is about 2.4." Nowhere is this specific optimum pH taught or suggested. Claim 9 recites in pertinent "....wherein said reaction temperature is between about 160°C and about 175°C", while claim 10 recites in pertinent part: "... wherein said reaction temperature is about 170°C." Bulfer mentions a highest temperature of about 149° C, while Ohkuma fails to teach the pH levels or whiteness levels for the temperature ranges claimed in the subject application. The foregoing reaction parameters and pH ranges are also recited in claims 18 -20 in differing combinations. Claim 15 recites in part: "...said percentage yield of said resistant starch is greater than about 50%," while claim 16 recites in part: "... wherein said yield of said resistant starch is greater than about 60%." Neither reference teaches a yield of starch in the recited levels in combination with the whiteness, temperature and pH ranges recited by Applicant.

Neither Ohkuma nor Bulfer, alone or in combination teach or suggest each and every element of the claimed invention. Indeed, each cited reference specifically teaches away from the claimed invention. Accordingly, Applicant respectfully requests withdrawal of the rejection of claims 1, 3, 4, 6, 7, 9 10, 12-16, 18-24, 26 and 27 under 35 U.S.C. §. Favorable consideration and notice of allowance are earnestly requested.

CONCLUSION

Applicant submits that claims 1, 3, 4, 6, 7, 9 10, 12-16, 18-24, 26 and 27 of the subject application recite novel and non-obvious methods for producing a white dextrin. Accordingly, reconsideration of the rejection and allowance of claims 1, 3, 4, 6, 7, 9 10, 12-16, 18-24, 26 and 27 at an early date are earnestly solicited.

If the undersigned can be of assistance to the Examiner in addressing issues to advance the application to allowance, please contact the undersigned at the number set forth below.

Respectfully submitted,

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